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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,290

05/09/2005

Toshiyuki Takasu

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SUGHRUE-265550  
2100 PENNSYLVANIA AVE. NW  
WASHINGTON, DC 20037-3213

EXAMINER

RAE, CHARLESWORTH E

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/534,290	<b>Applicant(s)</b> TAKASU ET AL.	
	<b>Examiner</b> Charleswort Rae	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/12/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's arguments/amendment, filed 8/2/07, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Applicant's statements that:

i) claims 1-10 are amended to even more clearly recite the claimed subject matter;

ii) support for the amendments may be found throughout the originally filed specification, for example, at pages 6-7 and 9;

iii) as stated at the sentence bridging pages 7-8 of the original specification, "the active ingredient of the present invention is useful, in addition to treatment of diabetes, as an agent for prevention and treatment of other diseases and at page 9, lines 16-18, that the "active ingredient of the present invention has been found to be useful as a remedy for overactive bladder which is a new use, and

iv) no new matter is added by the amendment,  
are acknowledged and made of record.

This action is made final.

### ***Status of Claims***

Claims 1-8, 12, 14-21, and 24 are pending in this application and are the subject of the Office action.

Claims 1-8, 12, 14-21, and 24 are withdrawn for being directed to non-elected subject matter.

Claims 9-11, 13, 22-23, and 25 are presented for examination.

### **Claim to Priority**

Receipt of applicant's non-English foreign priority document (i.e. Japanese Application No. 2002-323792, filed 11/7/02, and published 11/4/03), received 5/29/05, is acknowledged and made of record. In the absence on a certified copy of an English translation of the foreign priority application, the effective filing date for the instant claims is considered to be November 4, 2003, for prior art rejection purposes.

### **Information Disclosure Statements**

Applicant's information disclosure statement filed 6/12/07 has been considered and made of record.

### **Response to applicant's arguments/remarks**

#### **Nonstatutory Obviousness-Type Double Patenting (ODP) rejections (claims 1-10)**

Applicant contends that the rejection should be withdrawn for the following reasons:

1) The '532 patent (US Patent 6,346,532) is directed to amide derivatives represented by the general formula I and are disclosed to be useful as a diabetes remedy (see abstract); the amide derivative of the '532 patent are disclosed to accelerate insulin secretion and enhance insulin sensitivity, along with having antiobesity and antihyperglycemic action. However, the '532 patent does not teach or suggest the presently claimed method of treating overactive bladder by administering

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acetic acid anilide of the present invention (see col. 10, lines 23-29). The claimed method of treating overactive bladder was not within common knowledge or common sense of one of ordinary skill and it would not have been obvious to one of ordinary skill in the art at the time the instant invention was made.

2) Similar to the '532 patent, copending application 10/494,018 (Appl. '018) is directed to a remedy for diabetes using an alpha or beta-form crystal of an acetanilide. The claimed method of treating overactive bladder was not within common knowledge or common sense of one of ordinary skill and it would not have been obvious to one of ordinary skill in the art at the time the instant invention was made.

In response, the rejection is withdrawn with respect to the provisional rejection based on copending application 10/494,018 in view of the instant claim amendment (i.e. method claims).

However, the rejection is maintained with respect to '532 patent for the following reasons:

a) Anticholinergic therapy remains a cornerstone for treatment of overactive and neurogenic bladders that fail to store properly as evidenced by the teaching of Elliot et al. (Elliot et al. Mayo Clin Proc. April 2001;76:353-355, see especially page 353, col. 2, last full para).

b) The most common cause of urinary incontinence in elderly men and women is overactive bladder as evidenced by the teaching of Cecil Textbook of Medicine. 2000, vol. 1, pages 23-24, and 637-642, especially page 23, col. 1, last para and page 640, col. 1, 3<sup>rd</sup> para). Cecil's teaches that urge incontinence is the most common and

bothersome symptomatic type of urinary incontinence in the geriatric population and is usually associated with other symptoms of bladder overactivity such as daytime frequency and nocturia; men, diabetics, and patients with neurologic disorders are at highest risk for this type of urinary incontinence (page 640, col. 2, 4<sup>th</sup> para).

c) Research has found that the prevalence of overactive bladder (OAB) increases with age and that older adults are more likely to have OAB with urge incontinence as evidenced by the teaching of Wagner et al. (Wagner et al. Health-Related consequences of overactive bladder. The American Journal of Managed Care. December, 2002; 8(19, Sup):S598-S607; see especially page S599, col.1, first para).

d) Individuals with OAB have been found to have a higher prevalence of diabetes and congestive heart failure as evidenced by the teaching of Wagner et al. (Health-Related consequences of overactive bladder. The American Journal of Managed Care. December, 2002; 8(19, Sup):S598-S607; see especially page S600, col.2, last para to page S601, first col., first para).

e) Urinary incontinence is a common manifestation of benign and malignant prostate enlargement in middle-aged and older men (page 640, col. 1, 3<sup>rd</sup> para).

Clearly, the diabetic patient population and the instant targeted treatment population overlaps as evidenced by the teaching of the prior art (i.e. above items a-e). To the extent that the treatment population overlaps with the diabetic patient population, coupled with the fact that the only active method step is the administering of a known drug for treating diabetes, the contemplated treatment effects in practicing the instant

claimed method are deemed to be inherent characteristics of the instant claimed method.

Rejection under 102(b) (claims 1-10)

Applicant contends that this rejection should be withdrawn because:

1) Maruyama et al. (WO 99/20607; which corresponds to the '532 patent) is directed to amide derivatives represented by the general formula I and that are disclosed to be useful as diabetes remedy (see abstract of '532 patent).

In response, this rejection is maintained for the above identified reasons (i.e. (items a-e).

**REJECTIONS**

***Nonstatutory Obviousness-Type Double-Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 13 in view of claim 6 of U.S. Patent 6,346,532 ('532), in view of Cecil Textbook of Medicine. 2000, vol. 1, pages 23-24, and 637-642, especially page 23, col. 1, last para and page 640, col. 1, 3<sup>rd</sup> para). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are either anticipated by, or would have been obvious in view of the referenced claims. In particular, reference claim 13 is directed to a method of treating diabetes comprising administering a compound having the same general formula which encompasses the compound species recited in instant claim 1; reference claim 6 of reference '532 is drawn in part to the instant claimed compound: (R)-2-(2-aminothiazol-4-yl)-4'[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide.



The above discussion of Cecil's in connection with Response to applicant's argument/response regarding the ODP rejections is incorporated by reference.

Thus, claims 1-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 13 in view of claim 6 of U.S. Patent 6,346,532 ('532) in view of Cecil's.

### **Claim rejections – 35 USC 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 USC 102(b) as being anticipated by Maruyama et al. (WO99/20607; equivalent English translation U.S. Patent 6,346,532 B1). Maruyama et al. teach the instant claimed composition comprising compound (R)-2-(2-aminothiazol-4-yl)-4'[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide (see claim 6 and Example 36) recited in instant claims 1 and 6. Maruyama et al. teach methods for treating diabetes comprising administering an effective amount of the drug for treating said diabetes. Instant claim 1 recites "[a] method for treating overactive bladder." To the extent that the diabetic population overlaps with the instant claimed overactive bladder treatment population as evidenced by the teaching of Cecil's, as discussed above in connection with the Response to applicant's arguments/remarks, the contemplated treatment effects in practicing the instant claimed invention are deemed to be inherent

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features of administering (R)-2-(2-aminothiazol-4-yl)-4'[2-(2-hydroxy-2phenylethyl)amino]ethyl]acetanilide. The limitations with respect to "overactive bladder is a result of benign prostatic hyperplasia," as recited in claims 2 and 7; "wherein the subject has urinary urgency," as recited in claims 3 and 8; "wherein the subject as urinary incontinence," as recited in claims 4 and 9; "wherein the subject has pollakiuria," as recited in claims 5 and 10, are deemed to be inherent characteristics of practicing the instant claimed method.

Thus, claims 1-10 are found to be anticipated.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

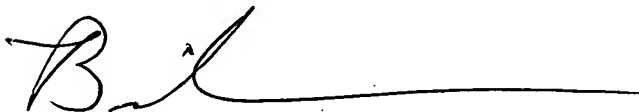
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10 November 2007  
CER

BRIAN-YONG S. KWON  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'B. Kwon', followed by a long horizontal line extending to the right.